APR 2 6 2001

510(k) Summary of Safety and Effectiveness

K010259

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

Date Prepared:
January 12, 2001

Submitter's Information: 21 CFR 807.92(a)(1)

Mediface Co., Ltd
997-4 Daechi-Dong, 5th floor
Kangnam-Ku
Seoul, Korea 135-280

Trade Name, Common Name and Classification: 21 CFR 807.92(a)(2)

Trade Name:	MEDIFACE™ PACS System
Common Name:	Picture Archiving Communications System
Device Classification:	892.2050
Name:	System, Image Processing

Predicate Device: 21 CFR 807. 92(a)(3)

Manufacturer:	Samsung SDS Co. Ltd
Device:	RAYPAX™ Display Workstation
510(k) Number:	K992306
Date Received:	07/09/1999
Decision Date:	09/22/1999
Decision:	Substantially Equivalent

Panel Code device reviewed by: Radiology
Panel Code device classified by: Radiology

Product Code:	LLZ
Classification:	Class II - 892.2050

Device Description: 21 CFR 807 92(a)(4)

The MEDIFACE™ PACS System handles various objects in a Picture Archive and Communication System (PACS) environment. These objects can be images, requests, patients, examination etc. PACS transmits digital electronic images and generates reports over a high-speed network to centralized storage. After transmission, patient information and images are available throughout the facility to many users simultaneously.

Indications for Use: 21 CFR 807 92(a)(5)

The MEDIFACE™ PACS System is a device that receives digital images and data from various sources (including but not limited to CT scanners, MR scanners, ultrasound systems, R/F Units, computed & direct radiographic devices, secondary capture devices, scanners, imaging gateways or other imaging sources). Images and data can be stored, communicated, processed and displayed within the system and or across computer networks at distributed locations. Typical users of this system are trained professionals, including but not limited to physicians, nurses, and technicians.

Technological Characteristics: 21 CFR 807 92(a)(6)

The device does not contact the patient, nor does it control any life sustaining devices. A physician, providing ample opportunity for competent human intervention interprets images and information being displayed and printed.

Conclusion: 21 CFR 807 92(b)(1)

The 510(k) Pre-Market Notification for MEDIFACE™ PACS contains adequate information and data to enable FDA - CDRH to determine substantial equivalence to the predicate device. The MEDIFACE™ PACS system has been and will be manufactured in accordance with the voluntary standards listed in the enclosed voluntary standard survey. The submission contains the results of a hazard analysis and the potential hazards have been classified as Minor.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 6 2001

Mediface Co., Ltd.
c/o Mr. Carl Alletto
Otech, Inc
2001 East Oak Shores Drive
CROSSROADS TX 76227

Re: K010259
MEDIFACE™ PACS
Dated: January 29, 2001
Received: January 29, 2001
Regulatory Class: II
21 CFR §892.2050/Procode: 90 LLZ

Dear Mr. Alletto:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure (s)

(Indications for Use Form)

510(k) Number: K010259

Device Name:
Mediface Co. Ltd. MEDIFACE™ PACS System

Indications for Use:
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Typical users of this system are trained professionals, including but not limited to physicians, nurses, and technicians.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

David A. Lazarus

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K010259